

## REMARKS

This is meant to be a complete response to the Final Office Action mailed March 19, 2010. Regarding the acceptability of an Amendment after a final rejection, 37 C.F.R. 1.116 states that: (1) an amendment may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office Action; or (2) an amendment presenting rejected claims in better form for consideration on appeal may be admitted. Applicants respectfully submit that the subject amendment complies with one or more conditions of (1)-(2) above, and thus the amendment fully complies with 37 C.F.R. 1.116. Therefore, entry of said Amendment after final rejection is respectfully requested.

In the Office Action, the Examiner rejected Applicants' claims 31-37, 45, 46, 49-51, 60 and 61 under 35 U.S.C. 112, second paragraph. Also in the Office Action, the Examiner rejected claims 31-37, 42, 45, 46, 48-51, 60 and 61 under 35 U.S.C. 103(a) as being unpatentable over US 5,482,841 in view of US 5,292,641, US 6,232,445, DiBrino et al. (Biochemistry 34(32):10130-10138 (1995)), and Zemmour et al. (J. Immunol. 148(6):1941-1948 (1992)) and by an admission in the specification at page 42 and Figure 7.

### Applicants' Response to the Written Description Rejection

In the Office Action, the Examiner rejected Applicants' claims 31-37, 45, 46, 49-51, 60 and 61 under 35 U.S.C. 112, second paragraph.

In response thereto, claim 31 (and thus claims 32-37, 45, 46, 49-51, 60 and 61 which depend therefrom) has been amended herein. Applicants respectfully submit that the amendments to the claims overcome said rejection. Therefore, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 112, second paragraph rejection of claims 31-37, 45, 46, 49-51, 60 and 61.

### Applicants' Response to the 35 U.S.C. 103(a) Rejection

In the Office Action, the Examiner rejected Applicants' claims 31-37, 42, 45, 46, 48-51, 60 and 61 under 35 U.S.C. 103(a) as being unpatentable over US 5,482,841 in view of

US 5,292,641, US 6,232,445, DiBrino et al. (Biochemistry 34(32):10130-10138 (1995)), and Zemmour et al. (J. Immunol. 148(6):1941-1948 (1992)) and by an admission in the specification at page 42 and Figure 7.

Applicants respectfully traverse the rejection based on the amendments to the claims and for the reasons of record in the previous response filed November 16, 2009, as well as the reasons stated herein below.

In response to Applicants' arguments against this rejection, which were presented in the Amendment filed November 16, 2009, the Examiner stated that:

Applicant argues that ... the previous technologies such as disclosed in '445 cited in the instant rejection have relied on strategies to artificially link the heavy chain and β2m plus or minus the peptide. However, the claim language (in case claim 31) does not preclude that the HLA class I molecule can not be a single chain molecule. The step of culturing recites "such conditions also allowing for endogenous loading of a peptide ligand into the antigen binding groove ... in the presence of β2-microglobulin", and β2-microglobulin is present in a single chain molecule. The obtaining steps do not preclude construction of a single chain MHC class I molecule, and the transitional language of the said base claim is "comprising". Thus, the claims do not recite that the heavy chain must associate with heterologous (i.e., cell derived) β2m, just that the conditions allow for endogenous loading of a peptide ligand in the presence of β2m prior to secretion of the trimolecular complex. Furthermore, "trimolecular complexes" recited in the instant claims is not defined in the instant specification. Hence, the instant claims are not limited to method steps that produce a heavy chain that is not fused to β2m. (Office Action, Page 6, lines 4-21)

Therefore, in response to the rejection, claim 31 (and thus claims 32-37, 42, 45, 46, 48-51, 60 and 61 which depend therefrom) has been amended herein to positively recite that the mammalian cell line expresses β-2-microglobulin, and said β-2-microglobulin is non-covalently associated with the individual soluble MHC heavy chain molecule and endogenously loaded, naturally produced peptide ligand to form the trimolecular complexes.

Thus, Applicants respectfully submit that the claims are non-obvious over the combination of US 5,482,841 in view of US 5,292,641, US 6,232,445, DiBrino et al. (Biochemistry 34(32):10130-10138 (1995)), and Zemmour et al. (J. Immunol. 148(6):1941-1948 (1992)) and by an admission in the specification at page 42 and Figure 7. Applicants respectfully request

reconsideration and withdrawal of the 35 U.S.C. 103(a) rejection of claims 31-37, 42, 45, 46, 48-51, 60 and 61 as being unpatentable over said combination of references.

## CONCLUSION

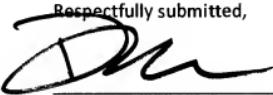
This is meant to be a complete response to the Final Office Action mailed March 19, 2010. As the Amendment complies with one or more requirements of 37 C.F.R. 1.116, Applicants respectfully request that the Amendment and Response be entered into the record.

Applicants respectfully submit that each and every rejection of claims 31-37, 42, 45, 46, 48-51, 60 and 61 has been overcome. Further, Applicants respectfully submit that said claims are patentable over the art of record, and are now in a condition for allowance. Favorable action is therefore solicited.

In addition, upon allowance of any of the generic claims 31-33, 35-37, 42, 45-46, 48-51 and 60-61, Applicants respectfully request rejoinder and reconsideration of currently withdrawn claims 38-41. Applicants respectfully submit that claims 38-41 are also patentable over the art of record and in a condition for allowance. Favorable action is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning this amendment or any other matter, Applicants' representative will welcome the opportunity to discuss same with the Examiner.

Respectfully submitted,



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